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TITLE: Telephone-Delivered Cognitive Behavioral Therapy for Chronic Pain Following Traumatic Brain Injury

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14. ABSTRACT

The purpose of this study is to evaluate the efficacy of a telephone-delivered cognitive behavioral treatment (T-CBT) in Veterans with a history of traumatic brain injury (TBI) for the treatment of chronic pain in a randomized controlled trial (RCT). Specifically, the RCT will examine the immediate (at the end of treatment) and long-term (6-months from randomization) efficacy of T-CBT on average pain intensity (primary outcome), and pain interference, sleep, depression, global impression of change, and life satisfaction (secondary outcomes) relative to a telephone-delivered pain psycho-educational active control condition (T-Ed). The study uses a 2-group parallel design. The sample will include 160 OEF/OIF Veterans with a history of TBI and chronic pain recruited from the VA Puget Sound Health Care System (VAPSHCS).

Recruitment and enrollment for the study is ongoing. Despite the delays in recruitment and enrollment, we believe we will be able to achieve our enrollment goals given 1) the commitment by VAPSHCS providers to help us achieve our recruitment goals, and 2) the large number of VAPSHCS patients that we project to be eligible and willing to participate.

15. SUBJECT TERMS
Traumatic brain injury(TBI), chronic pain, Veterans, telephone-delivered treatment, cognitive behavioral treatment

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Introduction

The purpose of this study is to evaluate the efficacy of a telephone-delivered cognitive behavioral treatment (T-CBT) in Veterans with a history of traumatic brain injury (TBI) for the treatment of chronic pain in a randomized controlled trial (RCT). Specifically, the RCT will examine the immediate (at the end of treatment) and long-term (6-months from randomization) efficacy of T-CBT on average pain intensity (primary outcome), and pain interference, sleep, depression, global impression of change, and life satisfaction (secondary outcomes) relative to a telephone-delivered pain psycho-educational active control condition (T-Ed) designed to control for time, dose, attention, and other nonspecific therapeutic effects such as therapeutic alliance. The study uses a 2-group parallel design. The sample will include 160 OEF/OIF Veterans with a history of TBI and chronic pain recruited from the VA Puget Sound Health Care System (VAPSHCS).

Keywords

Traumatic Brain Injury (TBI)
Chronic Pain
Veterans
Telephone-Delivered Treatment
Cognitive Behavioral Treatment (CBT)
Randomized Controlled Trial (RCT)

Overall Project Summary

Development:

Study personnel received full approval from the University of Washington's (UW) IRB March 25, 2013. The study received full approval from both the Veterans Affairs Puget Sound Health Care System's (VAPSHCS) Research and Development (R&D) Committee and Institutional Review Board (IRB) August 22, 2013. Study personnel submitted the protocol submission form and all pertinent IRB-approved materials to the US Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP) Human Research Protections Office (HRPO) on August 8, 2013. On April 9, 2014 the program manager, Ms. Kristen Katopol, informed study researchers that the approval authority at HRPO gave us approval to submit the revised protocol document to both the UW and VAPSHCS IRBs for approval. We received approval for the study protocol April 25, 2014 and May 14, 2014 from the UW and VAPSHCS IRBs, respectively. We received full HRPO approval June 13, 2014.

Research staff began the initial recruitment and screening process with prospective subjects shortly thereafter in the final week of June 2014.

The study PI has convened study meetings with study investigators on a bi-weekly basis as well as weekly meetings with the PI, the VA PI and key staff members to attend to pertinent recruitment and enrollment topics.

Preparation:
All steps with regards to preparation were completed in previous quarters. Mr. Gertz and both VAPSHCS research staff members have met on a continuous basis to review study procedures in anticipation of the recruitment and enrollment period.

Participant Enrollment and Data Acquisition
Enrollment for this study began in July 2014. As of October 24, 2014 we have enrolled 10 participants. We have assigned 8 participants to treatment intervention. Two participants have completed the treatment intervention and are in the follow-up period, 6 participants are participating in the study treatment phase, and 2 participants have been enrolled yet have not begun the treatment phase. Data acquisition continues for the study without difficulty. Drs. Hoffman, Williams, and Ehde meet with clinical staff on a weekly basis to provide supervision regarding clinical matters. Drs. Hoffman and Williams along with Mr. Gertz meet with research staff to discuss recruitment and enrollment strategies on a weekly basis. Finally, Dr. Hoffman conducts executive committee meetings on a bi-weekly basis to address issues regarding both treatment and enrollment.

Research staff attends regular clinician meetings to remind VAPSHCS clinicians about the study and its eligibility criteria.

Operations and Maintenance:
Researchers continue to submit quarterly progress reports to the Department of Defense (DoD). Researchers have obtained continuing IRB approval from both the UW and VAPSHCS IRBs and recently received continuing review approval from HRPO. Research staff continue to maintain personnel training files. Drs. Hoffman and Williams along with Mr. Gertz continue to supervise research staff to ensure adherence to procedures.

Data Management and Analysis:
Study databases have been completed. Research staff enters study data as it is collected from participants. Mr. Barber monitors the integrity of the research data on a regular basis.

Formative Evaluation:
The study PI and VA PI have developed a questionnaire to identify which data would be most relevant to stakeholders to move the intervention into practice. In addition, work has been started to develop an advisory group composed of both providers and Veterans with TBI. The initial purpose of the advisory group was to a) to collect data regarding current practice of pain treatment and b) identify current barriers to treatment for the study population. However, given the delay in getting HRPO approval, the advisory group will initially focus on strategies to assist with recruitment and secondarily to discuss data needed to move the intervention into practice.

Problems Encountered:

Considerable effort and time were expended to submit the VA IRB application. We had initially anticipated that the length of time required for submission caused a delay in subject recruitment and enrollment by approximately 1-2 months. However, additional delays were encountered when it took the VAPSHCS regulatory committees a considerable amount of time to review and approve the application (study personnel submitted the application in early January, and received full approval from the R&D committee August 22, 2013). We anticipated at that time that the length of time that elapsed for full VAPSHCS approval (over eight months) caused a delay in subject recruitment and enrollment by an additional 3-4 months.

After receiving approval from the VAPSHCS IRB and regulatory committee, we submitted the HRPO IRB application August 8, 2013. We first received notice October 8, 2013 that our application underwent initial administrative review. On October 10, 2013 we addressed the items raised in the initial review, yet did not hear back from HRPO staff regarding any substantive steps taken to complete the approval process for a considerable amount of time. We were later told that a personnel change at HRPO had occurred and our application was not assigned to an alternate individual. Given the delays in review, there was also some confusion regarding the versions of the protocol document that was submitted to HRPO. It took until April 9, 2014 for the program manager, Ms. Kristen Katopol, to inform us that the approval authority at HRPO had given us approval to submit the revised protocol document to both the UW and VAPSHCS IRBs for approval. We received approval for the study protocol April 25, 2014 and May 14, 2014 from the UW and VAPSHCS IRBs, respectively. We then finally received full HRPO approval June 13, 2014 (10 months after submission).

We believe the significant delay in getting HRPO approval caused significant delays in study recruitment and enrollment. We anticipate that the length of time that elapsed for full HRPO approval (10 months) has caused a delay in subject recruitment and enrollment by an additional 8-9 months, such that we are 15 months behind on recruitment and enrollment.

Recruitment and enrollment of research subjects commenced during the summer months of 2014. Unfortunately many providers we anticipated would refer subjects to research staff were out of the office or vacationing at that time.

We believe we will still be able to achieve our enrollment goals despite these delays given a) the research team consists of members with extensive experience in subject recruitment, b) the expressed commitment by VAPSHCS providers to help study personnel achieve their recruitment goals, 3) the large number of patients within the VAPSHCS that we project to be eligible and willing to participate, and 4) efforts to include the advisory board in assistance with strategies to maximize recruitment.

Key Research Accomplishments
Recruitment and enrollment for the study has begun and continues despite the considerable delays in obtaining IRB approval from both the VAPSHCS and HRPO.

Conclusion
We plan to make the following progress in the 1st quarter of the 3rd year of this research study.

Participant Enrollment/Data Acquisition:
Study personnel plan to recruit and enroll an average of about 9-10 subjects per month to offset study delays. Further, study personnel will continue to collect study data from subjects both in-person and via telephone. The study PI and investigators will provide ongoing supervision to research and clinical staff, as well as facilitate regular meetings with research staff and investigators to address enrollment issues.

As mentioned above, research staff attends regular clinician meetings to remind VAPSHCS clinicians about the study and its eligibility criteria. Dr. Williams plans to present study progress at regular in-service meetings on a regular basis to elicit clinician referrals. Research staff also plans to initiate approved recruitment activities to increase enrollment, including systematic medical record reviews of patients who have undergone a comprehensive traumatic brain injury evaluation within Rehabilitation Care Services (RCS) at the VAPSHCS to identify prospective participants.

Operations and Maintenance:
Dr. Hoffman, Dr. Williams and Mr. Gertz will continue to monitor study personnel performance to ensure adherence to procedures. In addition, Drs. Hoffman, Williams and Ehde will continue to conduct weekly meetings with study clinicians to address any clinical issues that may arise during treatment.

Data Management and Analysis:
Study personnel will continue to enter data as it is collected and conduct routine data checking.

Formative Evaluation:
The study PI and study personnel will consult with the Polytrauma and Blast-Related Quality Enhancement Research Initiative (QUERI) group and Tele-mental Health at VAPSHCS to assess important factors related to implementation. Further, study personnel will gather data from relevant stakeholders as well as the advisory board to assess which data will be necessary to assist with moving the intervention into practice.

Publications, Abstracts and Presentations
None to report.

Inventions, Patents and Licenses
None to report.

Reportable Outcomes
None to report.

Other Achievements
None to report.

References
None

Appendices

n/a